REMARKS

Claims 1-17, and 19-22 are pending.

Claims 1-17, and 19-22 were rejected.

Claims 1-2, 4-12, and 17 have been amended and new Claims 23 and 24 have been added, as discussed below. It is submitted that no new matter has been added to these claims. Support for the amendments to Claims 1-2 and 4-11 may be found, for example, at page 20, line 16. Support for the amendments to Claims 12 and 17 may be found, for example, at page 17, line 25 and at page 16, line 4, respectively. Support for new Claims 23 and 24 may be found, for example, at page 7, line 19, and at page 16, line 11, respectively.

Priority

The present application claims the benefit of prior-filed applications USSN 09/534,968; PCT/IL01/00284; PCT/IL02/00805; PCT/IL03/00303; IL 151,162; IL 152,366; and IL 153,753. The Examiner has suggested that these applications fail to provide adequate support or enablement, in accordance with 35 U.S.C. 112, for one or more claims of the application. Specifically, the Examiner has suggested that these applications do not disclose a balloon member comprising staves or a flexible band comprising a flow passage through which blood flows at a restricted rate as disclosed in Figure 5.

On consideration of the above rejection, Applicant has amended Claim 1 to recite "An intra-vascular balloon, comprising: a balloon body; and at least one springy and elongate rod, attached to said balloon body and conforming to a surface of said balloon body, such that said at least one rod can apply contact force to an object in contact with said balloon."

Additionally, applicant wishes to point out Claim 1 recites an intra-vascular balloon, which is illustrated in the present application, for example in Figs. 10 and 11. Support for this may be found, for example, in IL 151,162, at page 18, line 21, which states "Fig. 10 is an isometric view of a balloon catheter 1000 with expansion rods 1030 in accordance with an exemplary embodiment of the invention, that facilitates fine

adjustments in the configuration of a flow reducing implant 700 shown in a longitudinal section. In an exemplary embodiment, balloon catheter 1000 comprises a balloon 1010 connected to a hose 1020 that inflates and/or deflates balloon 1010."

The vascular implant recited in Claims 12 and 21 is shown, for example, in Fig. 5. Support for this may be found, for example, in IL 151,162, at page 16, line 5, which states that "Fig. 5 is an isometric view of a staved type flow reducing implant 530, in accordance with an exemplary embodiment of the invention, comprising staves 532, 534, 536 and 538 around a resilient membrane wall 502. Resilient membrane wall 502 of staved type flow reducing implant 530 is of a material and a thickness that allow it to readily project into flow passage 216 upon the movement of staves 532, 534, 536 and 538 toward each other. As flow reducing implant 530 assumes a compact state without, for example, trailing resilient material 502, staved type flow reducing implant 530 is easily positioned inside catheter 122 (Fig. 1) for removal and/or repositioning in coronary sinus 110."

Oath/Declaration

The Examiner has noted that Applicant has not complied with the requirements of 37 CFR 1.63(c), since the oath, declaration, or application data sheet does not acknowledge the filing of any foreign application or US application.

Accordingly, Applicant has sent the inventor a new declaration for signature, which will be forwarded to the Patent Office upon receipt.

Claim Objections

The Examiner has objected to Claim 17, which recites "a flow channel having an cross-section." This requires appropriate correction.

In view of this objection, Applicant has amended Claim 17 so as to correct this inadvertent error. It is submitted that this amendment to Claim 17 is purely cosmetic, and that no new matter has been added thereby.

Claim Rejections – 35 USC 112

Claims 1-11 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, as follows:

(i) Claim 1 recites an intra-vascular balloon comprising a balloon body and at least one stave attached to said balloon. However, the only reference to "staves" is directed to Figure 5 (see page 17, lines 24-31), where staves 532, 534, 536, and 538 are attached to a member made of shape memory material (see page 18, lines 1-4) , not a balloon. In contrast, Figure 10 shows a balloon catheter comprising a balloon, but no staves. Instead, the specification states that the balloon is attached to "expansion rods" (see page 20, lines 16-20). Therefore, the Examiner has stated that the specification does not support a balloon attached to staves.

(ii) Claim 1 recites that the stave and balloon are made from different materials. However, the Examiner has stated that the specification does not support this limitation since the specification does not positively recite two different materials.

On consideration of the above, Applicant has amended Claim 1 such that it recites "An intra-vascular balloon, comprising: a balloon body; and at least one springy and elongate rod, attached to said balloon body and conforming to a surface of said balloon body, such that said at least one rod can apply contact force to an object in contact with said balloon." Applicant has also amended Claims 2 and 4-11 so as to conform to amended Claim 1. It may be noted that the limitation that the rod and balloon are made from different materials, which has been deleted from Claim 1, has been added in new Claim 23. As noted above, support for new Claim 23 may be found, for example, at page 7, lines 19-20, which state that "the balloon and/or one or more staves comprise materials configured to reduce in size to a compact profile." Choosing the option of "or" from the phrase "and/or," if the balloon and staves are not both comprised of such a material, but only one of them is, then they must be comprised of different materials.

Claim Rejections – 35 U.S.C. 102

Claims 1-17 were rejected under U.S.C. 102(b) as being anticipated by Klein (U.S. Patent No. 5,863,284).

In response, it is submitted that there is no prima facie basis for the Examiner's assertion that these claims are anticipated by the teachings of Klein, as will be discussed below.

Klein teaches a device for radiation treatment of an internal body organ. The device comprises a radiation-emitting sleeve catheter (RESC) having a proximal portion 14, a central portion 16, and a distal portion 18 (column 12, line 40). The distal portion includes axial slits which allow the distal portion to be radially expanded so as to engage the walls of a blood vessel. The distal portion also includes a plurality of outside lumens 21, into which a plurality of elongate radioactive elements 30 are disposed. Optionally, metal bars may be placed in the lumens of the distal portion, in order to stiffen the distal portion. In operation, a balloon 32 is introduced via a port 24 in the central portion, the balloon being advanced along the catheter until it is disposed within the distal portion. Inflation of the balloon causes the axial slits to radially expand, such that the radioactive elements engage the blood vessel wall (Figs. 4a and 10).

The Examiner has suggested that Klein teaches "a balloon body (32) attached to staves (18)." As noted above, the "staves" are placed in the lumens of the distal portion of the device to Klein, but are not **directly** attached to the balloon 32, nor do they **conform** to the surface of the balloon 32. In contrast, Claim 1 recites "An intra-vascular balloon, comprising: a balloon body; and at least one springy and elongate rod, **directly attached to said balloon body and conforming to a surface of said balloon body**, such that said at least one rod can apply contact force to an object in contact with said balloon."

Additionally, Klein does not teach a "vascular implant, comprising: a flexible band having a diameter suitable for implantation in a blood vessel, surrounding a flow passage through which blood flows at a restricted rate when the implant is implanted in the blood vessel; and a plurality of elongate axial elements mounted on an outer surface of said band" (amended Claim 12). In contrast, Klein teaches a catheter device, not a vascular implant. Even if one were to consider the sleeve 48 shown in Fig. 10 to Klein as a "flexible band," this sleeve does not surround a blood flow passage through which blood flows. Instead, Klein's sleeve 48 is at first folded within the RESC device 10 and then unfolds (still within the RESC device) when the balloon is expanded (column 15, line 20). Since no blood flows within the RESC device, the sleeve does not surround a

blood flow passage through which blood flows. Blood does not, therefore, flow through the sleeve to Klein.

Further, Klein does not teach a "A blood flow reducing implant, comprising a body defining a flow channel having a cross-section which is restricted along its entire length in an axial direction, in which the smallest diameter of a cross-section is sized for passage of a guidewire and blockage of substantially all blood-flow therethrough" (amended Claim 17). Instead, Klein teaches a catheter device, not a blood flow reducing implant having a flow channel therein. The device taught by Klein is not suitable for use as a flow reducing implant.

In light of the above, it is submitted that amended independent Claims 1, 12, and 17 are not anticipated by Klein and are, therefore, allowable. It is further submitted that Claims (2-11), and (13-16) are allowable, as they depend from allowable amended Claims 1 and 12, respectively.

Claims 12-16 and 22 were rejected under U.S.C. 102(b) as being anticipated by Kavteladze et al. (U.S. Patent No. 5,683,411).

In response, in view of the amendment to Claim 12, it is submitted that there is no prima facie basis for the Examiner's assertion that these claims are anticipated by the teachings of Kavteladze et al., as will be discussed below.

Kavteladze et al. teach a number of vascular implants. One device, for use as a filter, comprises two coaxial, interconnected bodies of revolution, each defined by wires forming cells of, for example, a rhombic shape (column 3, line 56 and Fig. 1). The diameter of each body of revolution increases continuously in the axial direction from an apical end towards the opposite end which forms a base. A second device, for use as a vessel occlusion device, comprises two coaxial interconnected bodies of revolution, each defined by wires forming hexagonal cells (column 5, line 10 and Fig. 3). An elastic occlusion membrane 16 formed of an impermeable material is disposed at the apices of the two bodies. The device may be used for closing of a so-called ASD defect, i.e., a defect in the atrial septum between the right and left atria (column 6, line 3).

The Examiner has suggested that Kavteladze et al. teach "a flexible band (16) having a diameter suitable for implantation in a blood vessel and a plurality of elongate

axial elements (12) mounted on said band." However, the "axial elements" are not "mounted on an outer surface of said band," as recited in amended Claim 12. Instead of having rods that are part of the surface itself, Kavteladze et al. teach "axial elements" (as referred to by the Examiner) that extend through the membrane, as shown clearly in Fig. 3.

Additionally, Kavteladze et al. state (column 5, line 43) that his occlusion device "may completely obturate a vessel lumen due to the elastic membrane 16 which is reliably retained at the site of implantation by the self-expansion of the two bodies of revolution 10 and 11 assisted by the pressure gradient from the blood the flow of which is instantly blocked by the occlusion of the vessel." In contrast, amended Claim 12 recites a vascular implant comprising "a flexible band...surrounding a flow passage through which blood flows at a restricted rate."

In light of the above, it is submitted that independent amended Claim 12 is not anticipated by Kavteladze et al. and is, therefore, allowable. It is further submitted that Claims 13-16 and 22 are allowable, as they depend from allowable amended Claim 12.

Claims 17 and 20 were rejected under U.S.C. 102(b) as being anticipated by Ruiz (U.S. Patent No. 6,120,534).

In response, in view of the amendment to Claim 17, it is submitted that there is no prima facie basis for the Examiner's assertion that these claims are anticipated by the teachings of Ruiz, as he does not teach a device for achieving blockage of substantially all blood-flow therethrough," nor does he teach a device wherein the cross-section of the flow channel "is restricted along an axial direction," as recited in Claims 17 and 20. Instead, the device taught by Ruiz is expandable along its entire length (column 3, lines 58-61, and column 5, line 60 through column 6, line 3) and includes non-restricted sections, as, otherwise, if blood would not flow, the patient would die.

Ruiz teaches a stent 10 to be implanted in the pulmonary artery (column 3, line 25). The stent is formed of an expandable mesh 16 having lobed or conical portions 11 and 12 joined by a constricted region 13 (column 3, line 33). At least the interior surfaces 14 of the stent are covered with an elastomeric biocompatible material 15. The device does not entirely block blood flow, but regulates blood flow by restricting it to a degree.

It is clear, at least from Figs. 2a and 2b, that the cross-section of the stent varies along its entire length. As seen clearly in Fig. 2b, beginning at the leftmost edge of lobe 11, the cross-sectional dimension first becomes enlarged slightly, until the widest portion of lobe 11, then the cross-sectional dimension progressively decreases, until its constricted region 13, then the cross-sectional dimension becomes progressively enlarged again, until the widest portion of lobe 13, and finally the cross-sectional dimension decreases slightly, to the rightmost edge of lobe 13.

In contrast, amended Claim 17 recites a blood flow reducing implant, "in which the smallest diameter of a cross-section is sized for passage of a guidewire and blockage of substantially all blood-flow therethrough," and wherein the flow channel "is restricted along an axial direction."

In light of the above, it is submitted that amended Claim 17 is not anticipated by Ruiz and is, therefore, allowable. It is further submitted that Claim 20 is allowable, as it depends from allowable amended independent Claim 17.

Claims 12, 21, and 22 were rejected under U.S.C. 102(b) as being anticipated by Morris et al. (U.S. Patent Application Publ. No. 2004/0158280 A1).

In response, in view of the amendment to Claim 12, it is submitted that there is no prima facie basis for the Examiner's assertion that these claims are anticipated by the teachings of Morris et al., as will be discussed below.

Morris et al. teach a proximal actuator which is operable with various medical devices which have a tube or wire axially moveable with respect to another tube or wire. The actuator includes frame struts and a perforated filter material attached to the outside of frame struts, thereby forming a frusto-conical structure. The filter material 32 is typically a PET material having perforations therein (paragraph 0069).

While the Examiner has suggested that the device to Morris et al. is "a vascular implant," this is incorrect. Instead, Morris et al. teach an actuator for positioning various medical devices (paragraph 0065), for example, for positioning a balloon catheter (see Fig. 9 and paragraphs 0076 and 0087). In contrast, each of amended Claim 12 and Claim 21 recites a "vascular implant." While the device taught by Morris includes gold or platinum struts (paragraph 0067), which provide his device with firmness, this is in

contrast to the flexible band having axial elements mounted thereon, which comprise the vascular implant recited in Claims 12 and 21.

Additionally, as Morris et al. teach a filter material formed of PET (polyethylene terephthalate, it should be noted that the Website http://www.goodfellow.com/csp/active/STATIC/A/Polyethylene_terephthalate.HTML describes PET as "a hard, stiff, strong dimensionally stable material that absorbs very little water. It has good gas barrier properties and good chemical resistance except to alkalis (which hydrolyse it). Its crystallinity varies from amorphous to fairly high crystalline; it can be highly transparent and colorless but thicker sections are usually opaque and off-white." Morris et al. thus teach away from each of amended Claim 12 and Claim 21, which recites "a vascular implant comprising: a flexible band."

In light of the above, it is submitted that independent amended Claim 12 and Claim 21 are not anticipated by Morris et al. and are, therefore, allowable. It is further submitted that Claim 22 is allowable, as it depends from allowable amended Claim 12.

Claim Rejections – 35 U.S.C. 103

Claim 19 was rejected under 35 USC 103 (a) as being unpatentable over Ruiz (U.S. Patent No. 6,120,534). Applicant respectfully traverses this rejection.

As noted above, Ruiz teaches a stent having lobed or conical portions joined by a constricted region. The device is designed so as "to avoid the disruption of laminar flow through the stent" (column 4, line 11). In contrast, Claim 19 recites a blood flow reducing implant, "wherein the smallest diameter blocks over 95% of blood flow through the implant."

It is submitted that, since these limitations found in the Claim 19 are not taught by the cited art, Claim 19 is patentable.

All of the issues raised by the Examiner have been dealt with. In view of the foregoing, it is submitted that all the claims now pending in the application are allowable. An early Notice of Allowance is therefore respectfully requested.

Respectfully submitted,

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Enclosures:

- Request for Continued Examination (RCE)
- Petition for Extension (Three Months)